2010 Immunization Update: Part One: Children and Adolescents

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Disclosures

No financial conflict or interest with the manufacturer of any product named during this course.

Disclosures

- I will not discuss the use of vaccines in a manner that differs from the product insert, with the exception of PCV13 vaccine and HPV vaccines
- I will not discuss unlicensed vaccines

Objectives

After this presentation the provider should be able to

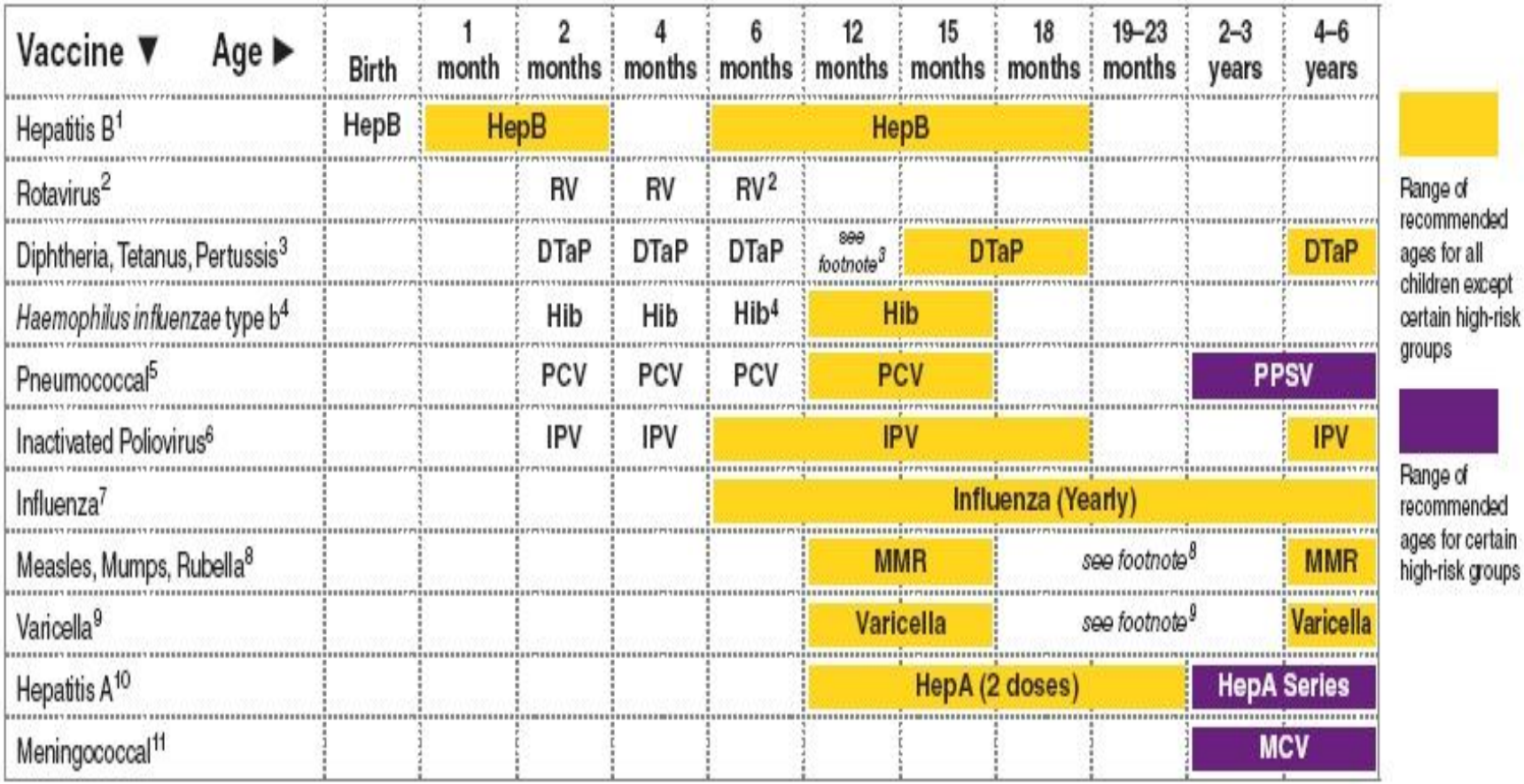
1. Schedule the routinely recommended vaccines for their patient population
2. Share the most recent ACIP recommendations with their colleagues
3. Decide whether to use combination vaccines

Overview

- 2010 Harmonized Schedule
- Combination vaccines
- Rotavirus vaccines
- Influenza vaccination
- Pneumococcal conjugate vaccine (PCV13)
- New human papillomavirus vaccine (Cervarix)

Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States • 2010

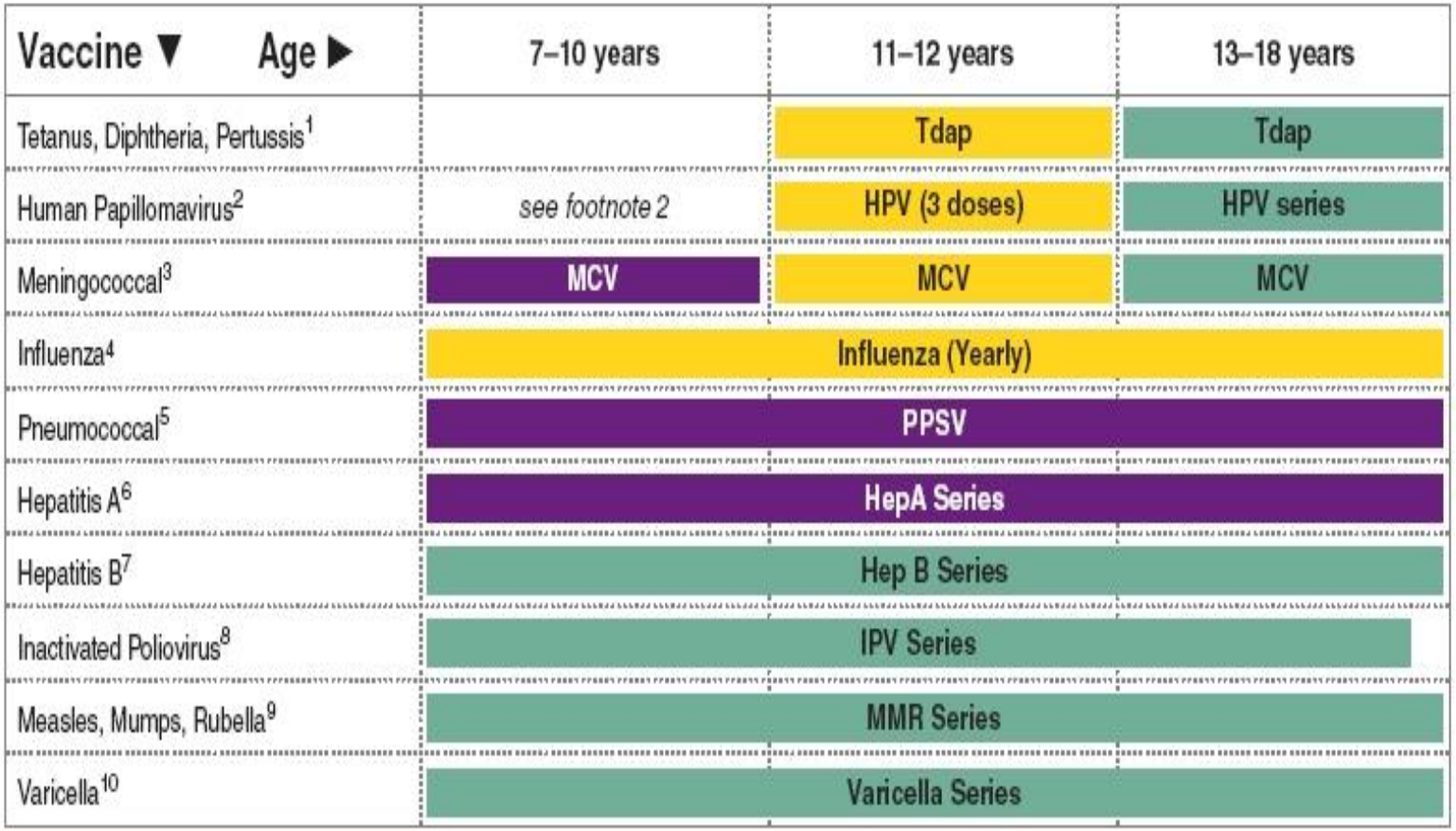
For those who fall behind or start late, see the catch-up schedule



This schedule includes recommendations in effect as of December 15, 2009. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Considerations should include provider assessment, patient preference, and the potential for adverse events. Providers should consult the relevant Advisory Committee on Immunization Practices statement for detailed recommendations: **http://www.cdc.gov/vaccines/pubs/acip-list.htm**. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS) at **http://www.vaers.hhs.gov** or by telephone, **800-822-7967**.

Recommended Immunization Schedule for Persons Aged 7 Through 18 Years—United States • 2010

For those who fall behind or start late, see the schedule below and the catch-up schedule



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Catch-up Immunization Schedule for Persons Aged 4 Months Through 18 Years Who Start Late or Who Are More Than 1 Month Behind—United States • 2010

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age.

PERSONS AGED 4 MONTHS THROUGH 6 YEARS

Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
Hepatitis B[1]	Birth	4 weeks	8 weeks (and at least 16 weeks after first dose)		
Rotavirus[2]	6 wks	4 weeks	4 weeks[2]		
Diphtheria, Tetanus, Pertussis[3]	6 wks	4 weeks	4 weeks	6 months	6 months[3]
Haemophilus influenzae type b[4]	6 wks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose) if first dose administered at age 12–14 months No further doses needed if first dose administered at age 15 months or older	4 weeks[4] if current age is younger than 12 months 8 weeks (as final dose)[4] if current age is 12 months or older and first dose administered at younger than age 12 months and second dose administered at younger than 15 months No further doses needed if previous dose administered at age 15 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 months through 59 months who received 3 doses before age 12 months	
Pneumococcal[5]	6 wks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose for healthy children) if first dose administered at age 12 months or older or current age 24 through 59 months No further doses needed for healthy children if first dose administered at age 24 months or older	4 weeks if current age is younger than 12 months 8 weeks (as final dose for healthy children) if current age is 12 months or older No further doses needed for healthy children if previous dose administered at age 24 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 months through 59 months who received 3 doses before age 12 months or for high-risk children who received 3 doses at any age	
Inactivated Poliovirus[6]	6 wks	4 weeks	4 weeks	6 months	
Measles, Mumps, Rubella[7]	12 mos	4 weeks			
Varicella[8]	12 mos	3 months			
Hepatitis A[9]	12 mos	6 months			

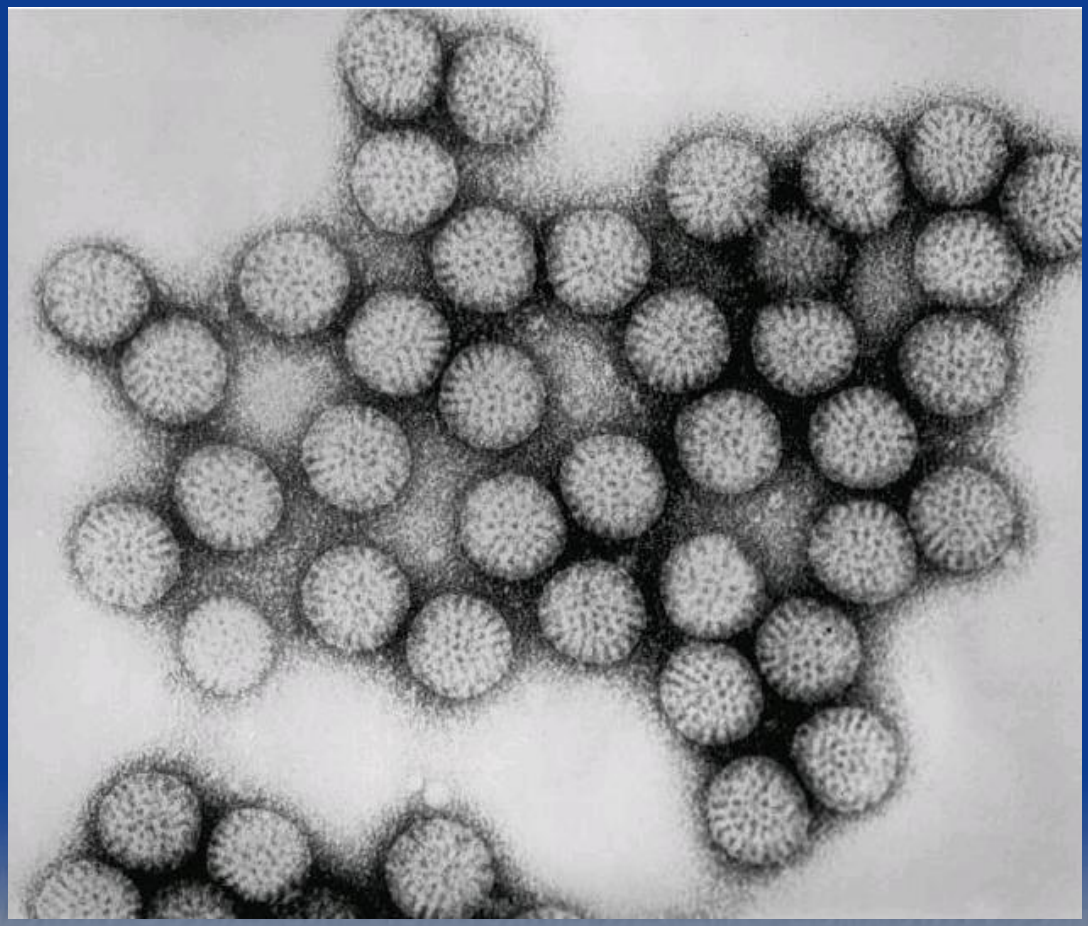
PERSONS AGED 7 THROUGH 18 YEARS

Tetanus, Diphtheria/ Tetanus, Diphtheria, Pertussis[10]	7 yrs[10]	4 weeks	4 weeks if first dose administered at younger than age 12 months 6 months if first dose administered at 12 months or older	6 months if first dose administered at younger than age 12 months	
Human Papillomavirus[11]	9 yrs	Routine dosing intervals are recommended[11]			
Hepatitis A[9]	12 mos	6 months			
Hepatitis B[1]	Birth	4 weeks	8 weeks (and at least 16 weeks after first dose)		
Inactivated Poliovirus[6]	6 wks	4 weeks	4 weeks	6 months	
Measles, Mumps, Rubella[7]	12 mos	4 weeks			
Varicella[8]	12 mos	3 months if person is younger than age 13 years 4 weeks if person is aged 13 years or older			

Rotavirus Vaccine

Live Vaccine

Altered Immunocompetence is generally a precaution for vaccination



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Monday, March 22, 2010, 15:54 EDT (03:54 PM EDT)
CDCHAN-00311-2010-03-22-ADV-N

Recommendation to Temporarily Suspend Usage of GlaxoSmithKline Rotarix (Rotavirus) Vaccine

Summary: The U.S. Food and Drug Administration (FDA) has learned that DNA from porcine circovirus type 1 (PCV1), a virus not known to cause disease in humans, is present in the Rotarix vaccine. All available evidence indicates that there has been no increased risk to patients who have received this vaccine. PCV1 is not known to cause any disease in animals or humans; therefore, it has not been routinely tested for in vaccine development. Rotarix has been extensively studied, before and after approval, and found to have an excellent safety record (i.e., no unusual adverse events). However, FDA is recommending that healthcare practitioners temporarily suspend usage of the Rotarix vaccine for rotavirus immunization in the United States while the agency learns more about the detection of components of

Reinstatement on Usage of Rotarix

- On March 22, 2010 the FDA recommended temporary suspension of usage of Rotarix rotavirus vaccine
- DNA from porcine circovirus type 1 (PCV1) virus was identified in both finished Rotarix and in the cell bank and seed virus
- FDA has since analyzed the findings in light of extensive safety record of Rotarix and RotaTeq
- On May 14, FDA announced that providers should resume use of Rotarix and/or continue using RotaTeq

ROTAVIRUS VACCINE

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 What is rotavirus?

Rotavirus is a virus that causes severe diarrhea, mostly in babies and young children. It is often accompanied by vomiting and fever.

Rotavirus is not the only cause of severe diarrhea, but it is one of the most serious. Before rotavirus vaccine was used, rotavirus was responsible for:

- more than 400,000 doctor visits,
- more than 200,000 emergency room visits,
- 55,000 to 70,000 hospitalizations, and

A virus (or parts of the virus) called porcine circovirus is in both rotavirus vaccines. This virus is not known to infect people and there is no known safety risk. For more information, see **www.fda.gov**.

3 Who should get rotavirus vaccine and when?

There are two brands of rotavirus vaccine. A baby should get either 2 or 3 doses, depending on which brand is used.

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Combination Vaccines Definition

A product whose components can be equally divided into independently available routine vaccines

Combination Vaccines – Definition - INCLUDES

Hib-HepB

DTaP/Hib

HepA-HepB

DTaP-HepB-IPV

MMRV

DTaP-IPV

DTaP-IPV/Hib

Use of Combination Vaccines

Pros	Cons
↓ number of injections	Higher costs
↑ timely coverage	Unnecessary doses
↓ costs of stocking & administering separate vaccines	Adverse events
↓ costs of extra healthcare visits	
Facilitate introduction of new vaccines & recommendations	

Combination Vaccines

The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Considerations should include provider assessment□, patient preference, and the potential for adverse events.

Provider assessment should include the number of injections, vaccine availability, likelihood of improved coverage, likelihood of patient return, and storage and cost consideration.

Influenza Vaccine Recommendations for the 2010-2011 Season

On February 24, 2010, ACIP unanimously approved a revision for the 2010-2011 influenza season

Influenza vaccination recommendations for adults were expanded to include all adults beginning in the 2010-11 influenza season

All people age 6 months and older are now recommended to receive annual influenza vaccination

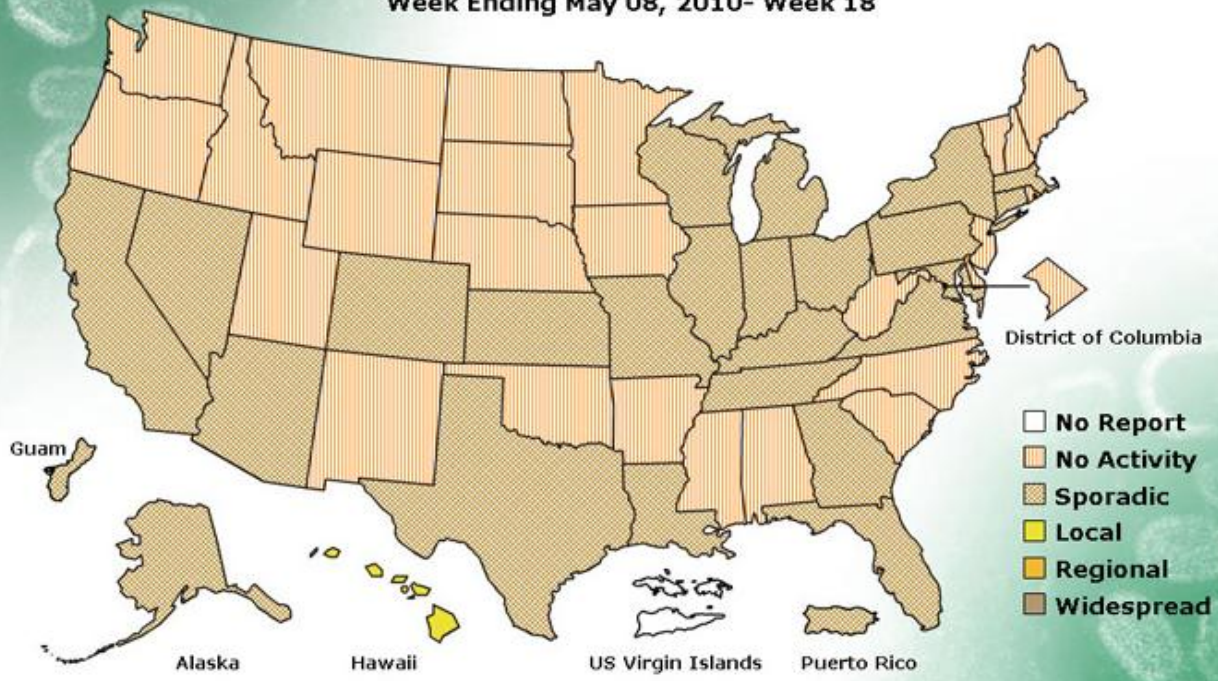
ACIP provisional recommendation, February 24, 2010

(Posted May 14, 2010, 7:00 PM ET, for Week Ending May 8, 2010)

FLUVIEW

A Weekly Influenza Surveillance Report Prepared by the Influenza Division
Weekly Influenza Activity Estimates Reported by State and Territorial Epidemiologists*

Week Ending May 08, 2010- Week 18



*This map indicates geographic spread and does not measure the severity of influenza activity.

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Influenza 2010

- Influenza virus continues to circulate in the United States
- Influenza activity has increased in several areas of the U.S.
- Almost all virus circulating now is the 2009 H1N1 (pandemic) strain
- Continue to vaccinate
- Check expiration date of vaccine before administration (some expire earlier than usual)

www.cdc.gov/flu/weekly

2009 H1N1 Influenza Vaccines Available in 2009-2010

Vaccine	Package	Dose	Age
sanofi pasteur	Multidose vial*+	Age-dependent	≥6 mos
	Single dose vial	0.25 mL	6–35 mos
		0.5 mL	≥36 mos
Novartis	Multidose vial+	0.5 mL	≥4 yrs
CSL	Multidose vial*+	Age-dependent	≥6 mos
	Single dose syringe*	0.25 mL	6-35 mos
	Single dose syringe*	0.5 mL	≥36 mos
GSK	Multidose vial	0.5 mL	≥18 yrs
Medimmune	sprayer	0.2 mL	2-49 yrs

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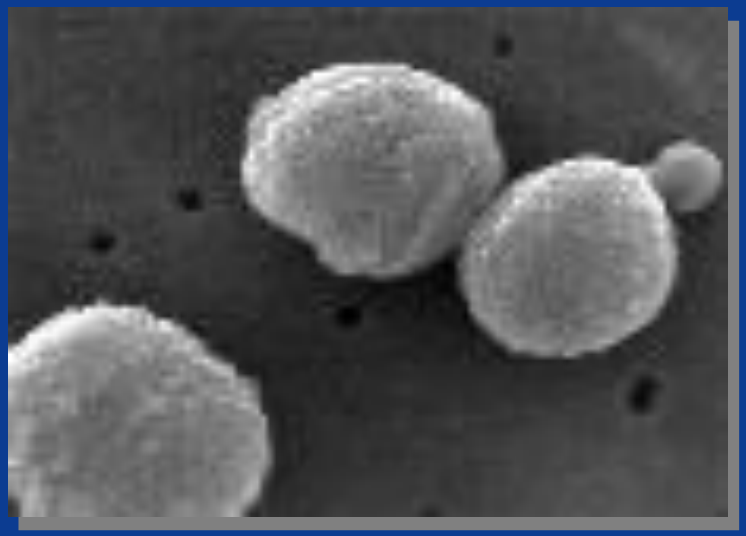
Live Attenuated Influenza Vaccine

- Intranasal
- Trivalent: same strains as TIV
- Attenuated: produce mild or no signs or symptoms of influenza
- Temperature-sensitive: do not replicate efficiently at 38°-39° C (temperature of the lower airways)
- Cold-adapted: replicate efficiently at 25° C (temperature of the upper airway)

Streptococcus pneumoniae



- Second most common cause of vaccine-preventable death in the U.S. (after influenza)
- Major clinical syndromes include pneumonia, bacteremia, and meningitis

Pneumococcal Conjugate Vaccines

PCV7 – Protein conjugated to polysaccharide from strains

4, 6B, 9V, 14, 18C, 19F, 23F

Pneumococcal Conjugate Vaccines

PCV13 – Protein conjugated to polysaccharide from strains

1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F

PCV13

- Manufactured by Wyeth (vaccine subsidiary of Pfizer)
- Trade name Prevnar-13
- Licensed February 25, 2010
- Approved for children 6 weeks through 5 years

PCV13 - Schedule

Routine recommended ages the same as PCV7

2, 4, 6 months, booster 12-15 months

Catch-up through 4 years for healthy children

Catch-up through 5 years for high-risk children

PCV13 - Schedule

- If the series is begun with PCV7, should finish the series with PCV13
- Do not discard PCV7 before expiration date!

Children Completely Vaccinated with PCV7

- A supplemental dose of PCV13 is recommended 8 weeks after the last dose of PCV7
- Extends to 5th birthday for healthy children (to 6th birthday for high risk)

Permissive Recommendation

Providers may vaccinate children 6 years through 18 years with one dose of PCV13 if they are high risk

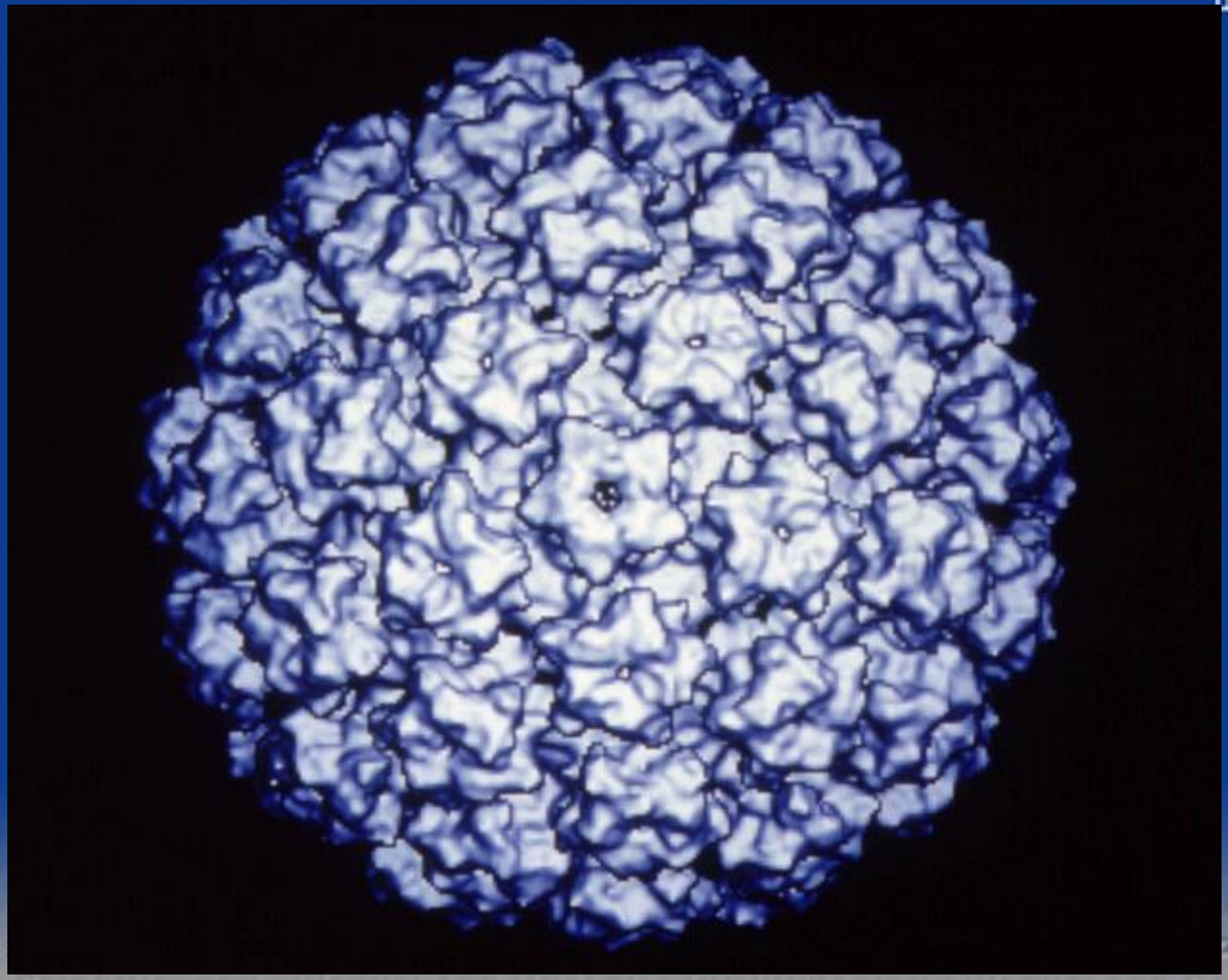
Asplenia

Immunosuppression

CSF leak

Cochlear implant

Human Papillomavirus



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Human Papillomavirus (HPV)

- Common sexually transmitted infection
- More than 100 types
- Established cause of cervical and other anogenital cancers
- Worldwide cervical cancer causes 233,000 deaths per year
- 4000 deaths in U.S.

HPV Disease Burden in the U.S.

Anogenital HPV is the most common sexually transmitted infection in the U.S.:

- ~20 million infected with HPV
- 6.2 million new HPV infections/year

Cates, STD 26:Supp 1-7 (1999); Meyers et al. Am J Epidemiol 151: 1158-1171 (2000)

Transmission and Risk Factors

- 24% of females in US sexually active by age 15 years, 40% by 16 and 70% by 18 years. Increased number of sex partners, increased predictor of infection
- Transmission of HPV through other types of genital contact in absence of penetration described, but less common

–(2002 National Survey Family Growth)

Human Papillomavirus Vaccines

	HPV Strains
HPV4 (Gardasil)	16, 18, (70% cervical other anogenital cancers) 6, 11 (90% genital warts)
HPV2 (Cervarix)	16, 18 (70% cervical cancers)

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Recommendations for Vaccination of Females

ACIP recommends routine vaccination of females aged 11 or 12 years with 3 doses of HPV vaccine. The vaccination series can be started as young as 9 years of age.

HPV vaccination is also recommended for females aged 13 through 26 years who have not been previously vaccinated or who have not completed the full vaccination series. Ideally, vaccine should be administered before potential exposure to HPV through sexual contact.

Provisional Recommendations for Vaccination of Females

- ACIP recommends vaccination with either the bivalent HPV vaccine or the quadrivalent HPV vaccine for prevention of cervical cancers and precancers.

- ACIP recommends vaccination with the quadrivalent HPV vaccine for prevention of cervical cancers and precancers, vulvar and vaginal cancers and precancers, and genital warts.

Provisional Recommendation*: Interchangeability of Vaccines

ACIP recommends that the HPV vaccine series be completed with the same HPV vaccine product whenever possible

However, if vaccination providers do not know or have available the HPV vaccine product previously administered, either HPV vaccine product can be used to continue or complete the series to provide protection against HPV 16 and 18

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*final recommendations pending CDC/HHS review and approval

Quadrivalent HPV Vaccine Efficacy Prevention of HPV 6, 11-related Genital Warts, Males 16-26 years

Endpoint	Vaccine n/N	Placebo n/N	% Efficacy (95% CI)
Genital warts	3/1245	28/1244	89 (66, 98)

Interim Analysis; per-protocol efficacy population, mean follow-Up 2.2 yrs, received all three doses of vaccine; naïve to vaccine type at baseline

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Ref: BLA, Presentation for VRBPAC Meeting, Sept 9, 2009

FDA Licensure: Indications for Quadrivalent HPV Vaccine in Males

Prevention genital warts due to HPV types 6 and 11

Approved for use in males aged 9 through 26 years

http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094042.htm

Provisional Recommendations* for Vaccination of Males

Recommendations:

Quadrivalent HPV vaccine may be given to males aged 9 through 26 years to reduce their likelihood of acquiring genital warts. Quadrivalent HPV vaccine would be most effective when given before exposure to HPV through sexual contact.

Vaccines for Children (VFC):

Quadrivalent HPV vaccine for males approved to be included in VFC enabling health care providers to obtain and provide vaccine but not actively promoting vaccination.

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*final recommendations pending CDC/HHS review and approval

Human Papillomavirus Vaccine

- High efficacy without evidence of infection with vaccine HPV types
- No evidence that the vaccine had efficacy against existing disease or infection (i.e., the vaccine is not therapeutic)
- Prior infection with one HPV type did not diminish efficacy of the vaccine against other vaccine HPV types

HPV Vaccine Special Situations*

Vaccine can be administered with:

- Equivocal or abnormal Pap test
- Positive HPV DNA test
- Genital warts
- Immunosuppression
- Breastfeeding

Cervical Cancer Screening

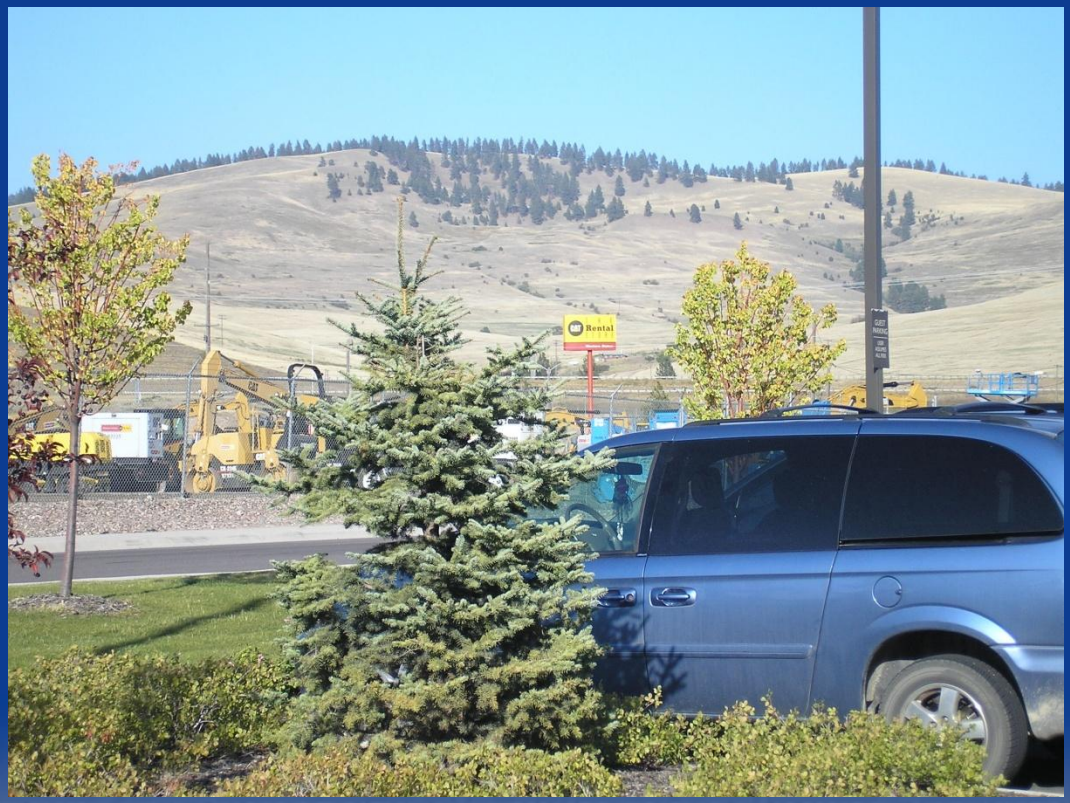
- Cervical cancer screening – no change
  - 30% of cervical cancers caused by HPV types not prevented by the HPV vaccine
  - Vaccinated females could subsequently be infected with non-vaccine HPV types
  - Sexually active females could have been infected prior to vaccination
- Providers should educate women about the importance of cervical cancer screening

Thank You

Hotline:
800.CDC.INFO

Email:
nipinfo@cdc.gov

Website:
www.cdc.gov/vaccines



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